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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/072,492	02/05/2002	Lorraine E. Pena	6193/1	2623

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EXAMINER
BENNETT, RACHEL M

ART UNIT	PAPER NUMBER
1615	7

DATE MAILED: 03/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/072,492	PENA ET AL.	
	Examiner	Art Unit	
	Rachel M. Bennett	1615	

-- The MAILING DATE of this communication app ars on the cover she t with the correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 December 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The examiner acknowledges receipt of Drawings and Preliminary Amendment filed 7/12/02,

Information Disclosure Statement filed 9/9/02.

Specification

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1, 11, 13, 25, 27, 35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant claim the particle has a particle size of 10μm or less. "Or less" reads on zero. It is suggested Applicants include a lower limit.

3. Claim 27 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants claim "at least one gram positive". It is unclear to the examiner what is gram positive, such as gram-positive bacteria, gram-positive cell, and gram-positive pathogen. Clarification is requested.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

5. Claims 1, 4, 6-7, 11, 13-14, 16, 18, 21, 25, 27-28, 30, 35 rejected under 35 U.S.C. 102(a) as being anticipated by Linder (WO 99/29299).

Linder discloses an administration form for acid-liable active compounds. The administration form is a suppository, in particular for rectal administration (see abstract). The amount (in %weight) of the active compound is advantageously 1-90% (see page 4). The particle size of the active compound is preferably in the range from 1-20 μm, particularly preferably in the range from 3-15 μm (see page 6). Suitable suppository bases, which may be used, are the hard fats customarily used for the production of rectal suppositories. Hard fats are mixtures of mono-, di- and triglycerides, which are obtained by esterification of fatty acids. Such hard fats are commercially available, for example, under the name Witepsol ® (see page 6). Examples of suitable antimicrobially-active ingredients include antibiotics, specifically clinamycin (see page 7). Therefore, these claims are anticipated.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1, 4, 6-16, 18, 21-28, 30, 33-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Linder et al. (WO 99/29299).

Linder discloses an administration form for acid-liable active compounds. The administration form is a suppository, in particular for rectal administration (see abstract). The

amount (in %weight) of the active compound is advantageously 1-90% (see page 4). The particle size of the active compound is preferably in the range from 1-20 μm, particularly preferably in the range from 3-15 μm (see page 6). Suitable suppository bases, which may be used, are the hard fats customarily used for the production of rectal suppositories. Hard fats are mixtures of mono-, di- and triglycerides, which are obtained by esterification of fatty acids. Such hard fats are commercially available, for example, under the name Witepsol® (see page 6). Examples of suitable antimicrobially-active ingredients include antibiotics, specifically clinamycin (see page 7). Linder does not specifically disclose Witepsol H32 Hard fat. Absent unexpected results, it is the position of the examiner it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the composition taught by Linder by substituting different hard fats depending on the desired melting point. It is well known high melting point Witepsol bases can be mixed with low melting point Witepsol bases to provide a wide range of possible melting ranges. Therefore, one of ordinary skill in the art would determine a suitable hard fat based on such factors as the active ingredient, the intended patient, and the patient's condition.

8. Claims 1-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Linder et al. (WO 99/29299), and further in view of Bergy et al. (US 3679787).

Linder discloses an administration form for acid-liable active compounds. The administration form is a suppository, in particular for rectal administration (see abstract). The amount (in %weight) of the active compound is advantageously 1-90% (see page 4). The particle size of the active compound is preferably in the range from 1-20 μm, particularly preferably in the range from 3-15 μm (see page 6). Suitable suppository bases, which may be

used, are the hard fats customarily used for the production of rectal suppositories. Hard fats are mixtures of mono-, di- and triglycerides, which are obtained by esterification of fatty acids. Such hard fats are commercially available, for example, under the name Witepsol ® (see page 6). Examples of suitable antimicrobially-active ingredients include antibiotics, specifically clinamycin (see page 7). Linder does not specifically disclose the lincosamide to be lincomycin.

Bergy et al. discloses the combination of lincomycin and spectinomycin, in unit dosage form, in combination with pharmaceutical carriers useful in treating diseased animals and exhibiting synergistic activity against mycoplasma infections (see abstract). The term "lincomycin" as used shall be taken to mean lincomycin free base and the pharmacologically acceptable acid addition salts thereof. The combination of lincomycin and spectinomycin is useful in combating many bacterial infections in man and animals. For these uses, the antibiotic compounds are dispersed in a pharmaceutically acceptable carrier, such as suppositories. For convenient and effective administration, lincomycin can be present in the selected dosage from in amounts ranging from about 50 to about 1000 mg (see cols. 1-2).

Absent unexpected results, it is the position of the examiner it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the composition of Linder by substituting the antibiotic lincomycin taught by Bergy for the antibiotic taught by Linder because of the expectation of obtaining a useful antibiotic in combating many bacterial infections in both man and animals as taught by Bergy. Both reference teach a suppository composition comprising antibiotics. Therefore, one would expect similar results without undue experimentation.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel M. Bennett whose telephone number is (703) 308-8779. The examiner can normally be reached on Monday through Friday, 8:00 A.M. to 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3592 for regular communications and (703) 308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

R. Bennett
March 12, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600